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Docket No. 1380-005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATIONS

Inventor: Virginia Freeman

Serial No.: 08/722,045

Group Art Unit: 1615

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Examiner: Spear, James M.

For: EFFERVESCENT PHARMACEUTICAL FORMULATIONS CONTAINING
CONTROLLED RELEASE BIODEGRADABLE MICROCAPSULES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

This Declaration is being filed to report the results of tests that were carried out to demonstrate that nano-particles having a diameter of between 200 and 400 microns could be maintained in suspension by Brownian motion. When particle sizes increase, the particles become so large that they rapidly drop to the bottom when they are suspended in a glass of water.

Particles below 200 microns can be difficult to prepare and the quantity of drug carried by particles of this size are quite low which could require the use of a quantity of a drug that could not be formulated in an effervescent tablet form.

This suspendability of nano-particles of from 200-400 micron was demonstrated experimentally by suspending in 200mL of tap water 200 mg of pellets of different sizes as follows::

	Quantity in weight of particles	Quantity of water	Time of suspension of particles in water (time required for sedimentation of all particles on the bottom of glass of water)
Particle size 200-400 micrometers (According to the present Invention)	200 mg	200 ml	60 seconds
Particle size 1000 1400 micrometers (Reference)	200 mg	200 ml	Less than 1 second

I Federico Stroppolo declare that the data provide above was obtained by actual laboratory experiments and I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application and of any patent issued thereon.

Dated: December 22, 2006



Federico Stroppolo